Pharmacy and Poisons Board

KENYA PHARMACOVIGILANCE NEWSLETTER

Ensuring Quality, Safety and Efficacy of Medicines for Better Healthcare

……. MORE GAINS IN PHARMACOVIGILANCE

Kenya Hosts First Global Conference on Pharmacovigilance

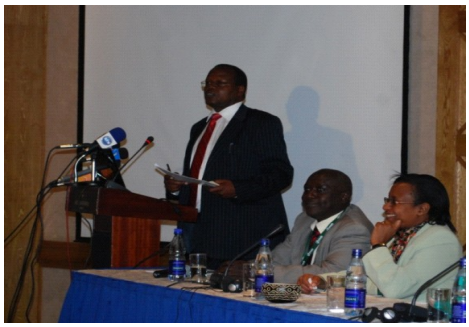
The first ever global conference in Kenya on Pharmacovigilance took place in August 2010. Over 100 delegates drawn from 30 countries participated in the conference which aimed at focusing attention to patient safety in the wake of increased access to treatment for AIDS, Malaria and Tuberculosis through various global initiatives. In addition, the conference provided participants with a framework for building, strengthening and optimizing pharmacovigilance systems at country level.

The conference was graced by top Kenya Government officials among them Minister for Public Service- Hon. Dalmas Otieno, Assistant Minister, Ministry of Medical Services—Hon. Samwel Kazungu, PS MoPHS —Mr. Mark Bor, DMS MOPHS- Dr. Shariff and Chief Pharmacist- Dr. Kipkerich Koskei.

Mr. Bor officially opened the conference and in his speech emphasized the significance of post market surveillance of medicines to chronicle long term effects unlikely to be observed during clinical trials.

He also noted that pharmacovigilance systems are beneficial for preventing drug-related morbidity and mortality, making savings on resources spent in healthcare costs and supporting better patient care.

"Many countries, he said, continue to be constrained in their medicine safety owing to weak legal frameworks, lack of regulatory structures and inadequate resources.



Permanent Secretary in the Ministry of Public Health and Sanitation Mr. Mark Bor officially opens the conference as Dr. Fred Siyoi, Pharmacy and Poisons Board and Dr. Mary Wangai, Chief of Party MSH/SPS Kenya look on.

On counterfeits, Mr. Bor expressed concern about the complexity of dealing with such products owing to the difficulty of identifying them. He noted that the enforcement of laws against counterfeits is the shared responsibility of government, regulatory authorities, importing and exporting agencies and even the media.

During the conference the first Kenya Pharmacovigilance Newsletter and Pharmacovigilance Fact Sheet were launched officially.

……..Read More on Page 4

Patient Safety Enhanced as a Result of Pharmacovigilance Reporting

Have you ever wondered whether your suspected ADR report or poor quality report makes any difference? While it may seem like a drop in the ocean, it definitely makes a difference!!

The Pharmacy and Poisons Board (PPB) has taken regulatory actions to enhance patient safety based on the receipt of over 1400 suspected ADR reports, poor quality reports from the field and results of Post Market Surveillance Surveys conducted since June 2009.

….Continued on page 2

Pharmacy and Poisons Board
Volume 1, Issue 2
February 2011

For previous issues of this newsletter, visit: www.pharmacyboardkenya.org

Special points of interest:

- *Senior Government officials emphasize the need for pharmacovigilance in enhancing patient safety*
- *PPB takes action: Withdrawals and recalls of several products due to quality and safety concerns*
- *Boosted sentinel surveillance for ART related ADRs takes off.*

Inside this issue:

Patient Safety Enhanced as a Result of Pharmacovigilance Reporting (Continued from Page 1)

Regulatory actions taken by PPB include withdrawal of all Rosiglitazone and Rosiglitazone containing products and Sibutramine and Sibutramine containing products from the Kenya market as a result of global safety concerns. Use of these products can lead to hepatitis and blood dyscrasias.

Various products have been recalled due to various quality related issues as listed below. In addition, a number of unregistered products (mainly anti-malarials) have been mopped from the market and subsequently destroyed.

Brand Name	Active Ingredient	Manufacturer	Batch No.	Reason for Recall
Utracaine Heavy Injection	Bupivacaine Hcl 5mg & Dextrose 80mg/ml	Jayson Pharmaceutical Ltd, Bangladesh	All batches	Complaints on lack of efficacy, products failed quality analysis
Minyua Oral Suspension	Mebendazole 100mg/5ml	Cosmos Ltd, Kenya	100299	Caking of suspension
Amoebazole Suspension	Metronidazole	Sphinx Pharmaceuticals, Kenya	0251M	Crystallization of suspension
Paracetamol	Paracetamol 500mg Tablets	For Shangai Pharma Ind. Ltd, China by Ningbo Shuangwei Pharmaceutical Co. Ltd	081201,090106, 081254,081219	Moulding and Discolouration
HePBQuin Injection	Hepatitis B immunoglobulin	Sanquin, Netherlands	08K20H506A	Package insert not complying to PPB requirements
Rihide—P Paediatric Tablets	Rifampicin 60mg/ Isoniazid 30mg	Cosmos Limited	080648, 080650, 080652	Products failed quality tests
Ethambutol/ Isoniazid Tablets	Ethambutol 400mg / Isoniazid 150mg	Svizera Europe BV	SL836, SL889	Products failed quality tests
Gentamicin Injection	Gentamicin 20mg/ml	Dawa ltd, Nairobi Kenya	0710304	Non-compliance to labeling requirements
Augpen Oral Suspension	Amoxicillin / Clavulanate potassium 156mg/5ml	Emcure Pharmaceuticals ltd, India	PFA 09008	Change of colour

Brand Name	Manufacturer	Reason for Mopping from the Market & Destruction
Co- Malasinin Tablets	Dawa Ltd, Nairobi Kenya	Unregistered
Arsun- AQ Tablets	Dawa Ltd, Nairobi Kenya	Unregistered
Arex Suspension	Gesto Pharmaceuticals Ltd	Unregistered
Lum-artem Oral Suspension	Comet Healthcare Ltd.	Unregistered
Co-fantrin Tablets	Comet Healthcare Ltd.	Unregistered
Daquinex Oral Solution	Comet Healthcare Ltd.	Unregistered
Artecure Tablets	Mepro Pharmaceuticals Ltd	Unregistered
Comether Tablets	Pharma Link Laboratories	Unregistered
Pharmasidar Tablets	Shanghai Pharmateq	Unregistered
Artefantrine Tablets	NBSW Pharma Ltd	Unregistered
Quinine Tablets	Urnav B.V	Unregistered
Spectino 2g Inj	Dawa Ltd, Nairobi Kenya	Unregistered

Data from ADR reports is expected to provide substantial evidence to support future reviews of National Treatment Policies.

The Division of Medicines Information and Pharmacovigilance acknowledges that these actions would not have been taken without the information provided through pharmacovigilance reports.

PPB urges all pharmacovigilantès to uphold the reporting culture to support patient safety.

Kenya's Pharmacovigilance Story Goes Across the Borders

In September 2010, Kenya hosted the Fifth Meeting of the Africa Vaccines and Regulatory Forum (AVAREF). AVAREF's key goal is to ensure that all African countries have the basic infrastructure and set-up required to conduct clinical trials in their countries. Over 50 participants from 19 Anglo- and Francophone African countries were present. Representatives from other medicine regulatory authorities and partners such as US-FDA, Health Canada, European Medicines Agency and European and Developing Countries Clinical Trials Partnership (EDCTP) were also present.

XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

In the past six months, the Division of Medicines Information and Pharmacovigilance has played host to

Dr. Ateba of MOH Cameroun converses with Dr. Jayesh on the pharmacovigilance reporting system.

delegations from several countries. These included senior health officials from Afghanistan, Sierra Leone, Cameroun and Burkina Faso.

The officials were mainly interested in the process of establishing Kenya's Pharmacovigilance System and the lessons learnt amongst other issues.

XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

Prof. Dicky Akanmori of WHO-AFRO and Ms. Rosemary Tiernan of US-FDA graced two trainings of healthcare workers on Boosted Sentinel Surveillance in support of ART. They applauded the Department of Pharmacovigilance and its partners—NASCOP and MSH/SPS on the quality of training that was being provided.

" The world needs to hear you". Rosemary Tiernan

"This is surely one of the finest systems in Africa and the world for actively engaging health care providers on pharmacovigilance." Prof. Akanmori

Regional Highlights: Recognition of Pharmacovigilance Champions

North Eastern

In October 2010 Dr. Erick Ochieng and his colleagues set up a stand at the North Eastern Province Agricultural Society of Kenya (ASK) show to sensitize members of the public on Pharmacovigilance. Over 800 people visited their stand and received current information on Pharmacovigilance.

Dr. Erick Ochieng and colleagues provide information on ART and the national pharmacovigilance to members of the public during the North Eastern ASK Show.

Nairobi Province

District Health Management Team (DHMT) members from Nairobi Province underwent the National Pharmacovigilance Training in 2010. At the end of the training, DHMT teams developed action plans on activities they would implement following the training. 100% of the teams implemented their action plans which included feedback to other staff and distribution of Pharmacovigilance tools .

Mr. George Muthuri (PPB) and Mr. Kandie (PPB) at the MOMS stand during the Nairobi International Trade Fair

In October 2010, PPB staff displayed Pharmacovigilance materials and sensitized the public on medicine safety related issues at the Nairobi International Trade Fair. This sparked interest amongst senior health officials who are involved in policy development and implementation.

The current Permanent Sectretary, Ministry of Medical Services, Ms. Mary Ngari complemented the efforts of the PPB in ensuring safety of patients in Kenya and encouraged all to aim higher.

Nyanza Province

Staff at St. Camillus Hospital were trained on Pharmacovigilance and Sentinel Surveillance in September 2010. Following the training, the staff proceeded to document all retrospective data on medicine safety and have since sent over 600 reports to PPB!

Update on Sentinel Surveillance for the Kenya National ART

The Pharmacy and Poisons Board with support from MSH/SPS has assisted National AIDS and STI Coordinating Program (NASCOP) to set up 7 sentinel sites, to boost surveillance on ART related ADRs. Plans are underway to set up 5 additional sites.

The sentinel sites are expected to:

- Submit all suspected ADR Reports on a monthly basis (by 5th of every month)
- Report all serious unexpected ADRs: within 7days and Deaths: Within 48 Hours
- Emphasize ARV related ADRs
- Monitor trends of ADRs
- Determine how the ADRs have affected the adherence and treatment/preventive programs
- Monitor quality, completeness, and timeliness of medicine safety reporting
- Respond to adverse events related to anti-retroviral medicines (ARVs)
- Generate data to be used to evaluate performance of site
- Generate data/signal which may inform Cohort Event Monitoring (CEM)
- Compare data and overall reporting with other sites

So far, all the 12 sites identified and trained in Boosted Sentinel Surveillance for ART are actively reporting ADRs to PPB within the agreed timeframe. Kudos to all the sentinel surveillance teams!! During the Kenya PEPFAR Implementers 2010 meeting, a presentation was made on the National Pharmacovigilance System. Stakeholders expressed interest in riding on the gains made to improve safety of ARVs and other medicines.

PHARMACOVIGILANCE :BOOSTED SENTINEL SURVEILLANCE FOR ART AT CO-OPERATIVE RETREAT AND CONFERENCE CENTER 13TH - 17TH 2010

Some Feedback from the Trained Sentinel Site Staff

"After training the other staff members in PV and witnessing the response from them, it dawned on me that we are actually late in starting off on PV and that we should have done this way back in the 70s. It is now flowing in my blood. In fact it was like drinking from a fore hose. It wasn't just from a theoretical perspective, but also included "live" examples. I got the motivation and the tools that I need to make this practice a success. It was an eye-opener for me and my colleagues as well. I learnt a lot."

Paul Ndungu
Pharmacy Department
COGRI—NYUMBANI

Fact!
Currently more than 60% of suspected ADR reports received at PPB are ARV related

Brain Teaser: A case study on Management of ART Related ADRS

FK is a single mother bringing up her four children singlehandedly. She was put on a Nevirapine based regimen (NVP/3TC/TDF) for the treatment of HIV in Sept 2005. She developed elevated LFTs but no overt hepatitis. What would you do if she came to seek medical attention at your facility?

- She was given an Efavirenz based regimen thereafter but soon developed Steven Johnson Syndrome (SJS). The Efavirenz was quickly withdrawn. What would you do next?
- She was put on triple NRTI base regimen with ABC (recommended when using this kind of regime to include ABC). She had a hypersensitivity reaction to ABC. What are your options at this point?
- She was started on a regimen that included a PI (Lopinavir/r) .Thankfully this was done while she was admitted. Within hours of starting the new regimen, she was vomiting and had diarrhoea, fever, facial swelling and bronchospasm. What was the problem? How would you handle it?
- The symptoms resolved on administration of IV Hydrocortisone. What are your options for treating HIV in this patient in our set up? Another triple NRTI regimen? An NRTI based regimen? A PI based regimen?

Mail your answers to the Division of Medicines Information and Pharmacovigilance (pv@pharmacyboardkenya.org) for consideration in the next issue.

A Word from the 2010 Kenya August House on Pharmacovigilance

Honorable Minister Dalmas Otieno (left) and Assistant Minister Samwel Kazungu (right) during the cocktail.

Hon. Dalmas Otieno and Hon. Samwel Kazungu addressed the global conference delegates at a cocktail gathering. Hon. Dalmas Otieno, in his speech on behalf of the Rt. Hon. Raila Amolo Odinga, EGH, MP, the Prime Minister of the Republic of Kenya, noted that Kenya had made significant progress in the area of medication safety. A 'draft pharmaceutical quality assurance surveillance framework' has been put in place anchored on the Kenya Vision 2030 goal for the health sector. The framework provides for equitable and affordable quality medicines.

He urged scientific and medical communities in developing countries to demonstrate assertive leadership to spur governments to confront challenges of ensuring medicinal safety. Hon. Kazungu reminded participants of the importance of involving patients in identifying and reporting poor quality medicines. Citing the "Consumer Reporting System" for poor quality of medicines and adverse drug reactions, Mr. Kazungu stressed the need to educate patients and consumers as they are gatekeepers to their own health.

Pharmacovigilance Goes to Northern Arid Zones of Kenya

Participants listen to the facilitator keenly during one of the training sessions

The Pharmacovigilance training for the upper Eastern region was a showcase of diversity. The 5-day training on quality, safety and efficacy of medicines for better health care was conducted from 30th August to 3rd September 2010. The course was sponsored by the Pharmacy and Poisons Board and organized by the Division of Medicines Information and Pharmacovigilance in collaboration with the office of the Provincial Director of Medical Services, Eastern Province. Health workers from different levels of health delivery (level 2 to 4) and different cadres attended the training.

Participants were drawn from some of the most remote parts in Kenya such as Moyale at the Ethiopian border, Loyiangalani in Marsabit and Garbatulla in Isiolo among others. It provided a rare opportunity to share experiences on adverse drug reactions from the region and interact with the staff of the National Pharmacovigilance Centre.

In his opening remarks Dr. Kigondu, District Medical Services Officer (DMSO) Isiolo zone, urged participants to take the training course seriously as it would help deal with adverse drug reactions (ADRs), poor quality medicines and also the opening of reporting mechanisms to the medicines regulator in Kenya directly.

Prof Neeraj Sood of University of Southern California, USA also graced the training and was particularly interested in the implementation of pharmacovigilance in Kenya. It was evident that everybody played his/her part efficiently during the training and with lots of enthusiasm. The mean score proved this for the pretest was 76% and this proudly rose to 89% in post test.
The upper Eastern community is largely pastoralist with milk and meat being a common ingredient in their meals. An interesting discussion went around the potential of residents in the area experiencing adverse reactions following the intake of the animal products where the animals have been given medication and slaughtered before the residues clear from the system. With the knowledge on how to detect and monitor adverse drug reactions the participants are expected to report all cases.

Division of Medicines Information and Pharmacovigilance Staff at the banks of River Ewaso Nyiro following the training at Isiolo.

The staff of the National Pharmacovigilance centre had a nice time at Isiolo too. Besides sampling delicacies in different 'restaurants' in town, they also had a sight-seeing trip which took them to Archers Post and the banks of river Ewaso Nyiro, the only river that flows through the vast arid zone down to the Indian Ocean and camels being milked everywhere was an interesting site! The last day of training was filled with a somber mood- having made new friends and 5 intensive days of important and different discussions, the participants were reluctant to leave. Pharmacovigilance ensures safety of patients but also helps ***pharmacovigilantes*** make new friends.

Upcoming Events

- Stakeholders forum for dissemination of ARV and Anti– TB medicines Post Market Survey Results
- Monitoring of Poor Quality Medicines using mini-laboratory testing for Anti-Malarials

Work in Progress…..

- Guideline for Application to Conduct Clinical Trials in Kenya
- Strategy for Post Market Surveillance in Kenya
- Guidelines for Advertisement and Promotion in Kenya

Meet the team from Management Sciences for Health/ Strengthening Pharmaceutical Systems Program (MSH/SPS) that supports Pharmacovigilance Activities in Kenya.

MSH/ SPS recently paid a visit to PPB to receive a brief on the Division of Medicines Information and Pharmacovigilance's Annual Operating Plan. PPB appreciates support provided by MSH/SPS in advancing Pharmacovigilance in Kenya.

Pharmacovigilance Resources: What's new on the Pharmacovigilance Webpage?

The Division of Medicines Information and Pharmacovigilance has developed and provided several resources to enhance National PV activities. These include the

National Pharmacovigilance Guidelines, Revised National Training Curriculum, Pharmacovigilance Reporting Tools, job aids and IEC materials.
These can readily downloaded from the PPB website.

In addition, the Division continues to maintain E-shot- an innovative e-mail based means of communication through which the Division of Medicines Information and Pharmacovigilance can provide updates to the subscribers. Since the last issue of the newsletter, the following alerts have been sent out:

- Simvastatin—increased risk of muscle injury with high doses
- Approved circular for adopting new ARV guidelines
- Amoebazole suspension : crystallization and poor dispersion
- Suspension of market authorization of Rosiglitazone and rosiglitazone containing products
- Minyua suspension —caking of suspension
- Spinal Anaesthesia products—lack of efficacy and failed analysis
- Photosensitivity reactions resulting from a number of topical and systemic medicines
- Voluntary Recall of Polaramine Expectorant by MSD - mislabeling of dosing schedule for children between 2-6years

For more details on these alerts, visit www.pharmacyboardkenya.org

To subscribe to e-shot send an e-mail to: **mdaemon@pharmacyboardkenya.org** with the first line of the body of the mail (not subject line) of the email being: SUBSCRIBE ESHOT@PHARMACYBOARDKENYA.ORG

* The subject line is not necessary and can be left blank
* The first line of the body of the email is the most important and must be: **subscribe eshot@pharmacyboardkenya.org.** The rest of the email can be blank.
* The email must be sent to: **mdaemon@pharmacyboardkenya.org** not to **eshot@pharmacyboardkenya.org**

The Division of Medicines Information and Pharmacovigilance was set up in late 2004 at the Pharmacy and Poisons Board with a vision to develop, implement and continuously upgrade an appropriate system for detecting, reporting and monitoring adverse drug reactions (ADRs) and other relevant medicine related problems in Kenya. The department strives to ensure the safety and efficacy of pharmaceutical products in Kenya. The department also carries out routine post market surveillance on all medicines in Kenya which helps ensuring that the quality of these medicines also remains as required.

" All great journeys begin with a single step." The Pharmacy and Poisons Board is grateful to all stakeholders, partners and especially our 'pharmacovigilantes' for their active reporting and support to the National Pharmacovigilance System in Kenya.

For more information, please contact:

Division of Medicines
Information and Pharmacovigilance
Pharmacy and Poisons Board
Ministry of Medical Services
Lenana Road
P.O. Box: 27663-00506
Nairobi, KENYA

Email:
pv@pharmacyboardkenya.org
Website:
www.pharmacyboardkenya.org
Telephone:
(+254-20-) 3562107
(+254-0-) 733884411 / 720608811

Production of this newsletter was made possible through support provided to Management Sciences for Health by the U.S. Agency for Inter-national Development, under the terms of cooperative agreement number GHN-A-00-07-00002-00. The opinions expressed herein are those of the author (s) and do not necessarily reflect the views of the U.S. Agency for International Development.

About SPS
The Strengthening Pharmaceutical Systems (SPS) Program strives to build capacity within developing countries to effectively manage all aspects of pharmaceutical systems and services. SPS focuses on improving governance in the pharmaceutical sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to essential medicines.

"You need not be certain… just be suspicious"… Report all suspected ADRs and Poor Quality Medicines.

USAID FROM THE AMERICAN PEOPLE

Pharmacy and Poisons Board

msh Management Sciences for Health | SPS Strengthening Pharmaceutical Systems